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| liposom\$ same kit same (low adj2 water adj2 solub\$) | 0         |

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| <u>L3</u> | liposom\$ same kit same (low adj2 water adj2 solub\$) | 0  | <u>L3</u> |
| <u>L2</u> | L1 and (hydrophobic or lipophilic)                    | 6  | <u>L2</u> |
| <u>L1</u> | liposom\$ same kit same steriliz\$                    | 11 | <u>L1</u> |

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L1: Entry 10 of 11

File: USPT

Dec 10, 1996

DOCUMENT-IDENTIFIER: US 5583052 A  
TITLE: Formulation preparation device .

Abstract Text (1):

A formulation preparation device is provided herein which contains a valve assembly, transfer spikes, syringe port and tube, these components being interconnected so as to provide for controlled fluid flow between the spikes and port, through the assembly, in specific directions only. The device has an enclosed, sterilizable, gripable housing and can be used to mix combine fluids in reproducible and predetermined proportions. Combination is accomplished aseptically, avoiding contact between the device's operator and the fluids and the substances combined. Biologically active compounds can be combined with one or more fluids, including such aqueous liposome suspensions, using the device. A formulation preparation kit containing, in addition to the device, the fluids and compounds to be formulated is thus also provided herein; methods of using the device to prepare such formulations are further provided herein.

Detailed Description Text (32):

A preparation kit containing the device of this invention, sterilized, a vial containing egg phosphatidylcholine/cholesterol (EPC/Chol) liposomes (vial #1), a vial containing an aqueous buffer (vial #2) and a vial (vial #3) containing a doxorubicin hydrochloride/saline solution was used. Also used was a disposable syringe Protective caps were removed from the first and second transfer spikes ((B) and (C)), following which the vials were attached thereto, the beveled points piercing the covers of the vials. A protective cap was removed from the syringe port (E), and a Luer-Lok syringe was attached thereto. The syringe plunger was then drawn downward, completely emptying the contents of vials 1 and 2 into the syringe. The device was gently shaken to aid in mixing of the fluids in the syringe. A protective cap was next removed from the third transfer spike (D), to which the doxorubicin-containing vial was attached, piercing the receptacle's cover. The syringe's plunger was then infused upward, emptying the syringe's contents in the vial #3; this resulted in loading of the doxorubicin into the liposome. The receptacle was then removed, and the device, with vials 1 and 2 remaining attached thereto; was disposed of.

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